

Remarks

Claims 34-91 are pending in the subject application. By this Amendment, Applicant has added new claims 92-98. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example pages 5-6) . Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 34-96 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicant gratefully acknowledges the Examiner's withdrawal of the rejections under 35 U.S.C. §§ 112, first paragraph, and 101. Additionally, Applicant respectfully requests the courtesy of an interview in this matter prior to the issuance of another Office Action in this case.

Claims 34, 36-42, 50, 52-58, 75, 77-83, and 91 and claims 34-91 are rejected over 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action argues that: 1) the administration of the recited heat dose by heating hair follicles of the scalp of a human patient or the skin of a mammalian animal at about 39°C to 45°C for about 15 to 120 minutes is critical or essential to the practice of the invention; and 2) the administration of a chemotherapeutic drug within about 2 to 24 hours after the administration of the heat dose is critical or essential to the practice of the invention, but not included in the claims. Applicant respectfully asserts that the claims as filed are enabled by the subject specification and traverse the rejection.

Applicant notes that M.P.E.P. 2164.08(c) indicates that:

In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567, 191 U.S.P.Q. 429, 431 (C.C.P.A. 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

In the case of the instant invention, the Office Action points to no language within the specification that indicates that the time and temperatures for the application of the recited heat dose is “critical” or “essential”. Rather, the passage referred to indicates that “The ranges of heat dose that cause a detectable stress protein response in mammalian cultures is known and can serve as an initial guide for dose-finding studies. The typical range of elevated temperatures extends from about 39°C to about 45°C, and the typical duration of elevated temperature exposures is between about 2 hours and 15 min.”. Thus, contrary to the assertion in the Office Action, there is no discussion of any critical time requirement for the application of the recited heat dose and the claims recite the application of a heat dose that causes an increase in the concentration of at least one stress protein ... and that produces an increased resistance of the hair follicles to chemotherapeutic drugs ...”. . With respect to the alleged “criticality” of the time for application of the chemotherapeutic drug, the Office Action points to the paragraph bridging pages 5-6 in support of this allegation. Again, Applicant respectfully points out that there is no teaching that the administration of chemotherapeutic agent within 2 to 24 hours of the heat dose is critical or essential to the claimed invention. Indeed, the as filed specification clearly contains disclosure omitting these alleged “critical features” (see, for example, page 6, lines 7-12, page 19, line 29 through page 20, line 6, and the abstract). Accordingly, it is respectfully submitted that the claimed invention is enabled by the subject specification and withdrawal of the rejections is respectfully requested.

Claims 34, 36, 39, 50, 52, 55, 75, 77, and 80 are rejected under 35 U.S.C. § 102(b) as anticipated by Li *et al.* (U.S. Patent No. 5,830,177). The Office Action states that the Li *et al.* patent teaches compositions and treatment methods useful for the prevention of hair loss during chemotherapy. Applicant respectfully asserts that the Li *et al.* patent does not anticipate the claimed invention.

Applicant respectfully submits that the ‘177 patent fails to anticipate the claimed invention. For example, the reference clearly states that photosensitizing agents and the use of electromagnetic radiation to for the activation of the photosensitizing agents is for the ablation of hair follicles (see column 5, line 36 through column 6, line 13, see especially column 6, lines 5-8). The specific use of the photosensitizing agents and the electromagnetic irradiation is also discussed in the context of ablating hair follicles and the removal of hair at column 7, lines 13-23. Thus, it is respectfully

submitted that the reference fails to anticipate the claimed invention as it is directed to a method of removing hair or ablating hair follicles as opposed preserving hair follicles that are killed by a chemotherapeutic agent. Applicant also submits that chemotherapy is not administered after the electromagnetic exposure discussed in Example 1 of the '177 patent.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position. Applicant expressly reserves the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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